DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 10, 2014

Olympus Winter and Ibe GmbH
% Ms. Sheri Musgnung
Olympus Corporation of the Americas
3500 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K140624
Trade/Device Name: HICURA Hand Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 7, 2014
Received: November 10, 2014

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140624

Device Name
HICURA Hand Instruments

Indications for Use *(Describe)*
The Olympus hand instruments are specifically designed for endoscopic diagnosis and treatment during the thoracoscopic and laparoscopic procedures within the peritoneal and thoracic cavity.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary of Safety and Effectiveness

1. General information

- Applicant:
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  Germany

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  Establishment Registration No.: 2429304

- Manufacturer:
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- Registration number:
  9610773

- Contact person:
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  Email: holger.nadler@olympus-oste.eu

- Prepared Date:
  December 9, 2014

2. Device identification

- Proprietary name:
  HICURA Hand instruments
- Common name:
  Hand instruments
- Classification name:
  Electrosurgical cutting and coagulation and accessories, Endoscope and Accessories
- Regulations Number:
  21 CFR 878.4400 / 21 CFR 876.1500
- Regulatory class:
  Class II
- Product code:
  GEI, GCJ
- Device panel:
  General & Plastic Surgery

3. Predicate devices

K944200 / K944201; K984417 Olympus HiQ Hand Instruments; Bipolar Grasping Forceps BiQ+

4. Description of device

The Olympus hand instruments are specifically designed for endoscopic diagnosis and treatment during the thoracoscopic and laparoscopic procedures within the peritoneal and thoracic cavities.

The Olympus HICURA hand instruments are used for grasping, dissection, biopsy and cutting (scissors) under endoscopic visualization. Depending on their design every single jaw insert can be used for various applications. The variety of the jaw inserts, handles and shafts is defined by the different lengths of the instruments, handles styles and a large variety of jaw inserts. The Olympus HICURA hand instruments will be marketed as a completely assembled finished device which includes jaws with control rod, insulated rotatable shaft, and handle. Individual components such as jaws with control rod, insulated shaft, or handle will be available separately as modular components.

The HICURA hand instruments use a modular design in which each instrument can be disassembled into the following three pieces:

1. Handle
2. Outer Shaft/Insulation
3. Jaw insert with control rod

5. Indications of use

The Olympus hand instruments are specifically designed for endoscopic diagnosis and treatment during the thoracoscopic and laparoscopic procedures within the peritoneal and thoracic cavities.

6. Comparison of Technological characteristics

The HICURA hand instruments share virtually all specifications and design characteristics of the predicate devices. The HICURA hand instruments and predicate devices are HF-surgical instruments intended for grasping, dissection, biopsy, and cutting under endoscopic visualization. The HICURA hand instruments are easier to assemble/disassemble and more convenient in terms of ergonomics, thus have improved usability over the predicate devices.

7. Performance Testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO-14971:2007.

Performance tests were carried out to ensure that the system functions as intended and meets design specifications. The following performance tests and usability studies were conducted:

Basic safety and performance testing was performed in accordance with international approved technical standards such as IEC 60601 (see list below).

Additional testing was conducted to evaluate the mechanical and functional performance including tensile strength, bending strength, assembly/disassembly, grasping force, shaft rotation, dielectical strength, electrical resistance, leakage current, transport and storage conditions, reprocessing and usability (ergonomics, assembly/disassembly, shaft rotation, color coding, overall design confidence).

Reprocessing validation was carried out in accordance with "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance – April 1996."

The following standards have been applied to the HICURA hand instruments:

DIN EN ISO 14971:2007	[Recognition Number 5-40]
EN ISO 10993-1: 2009	[Recognition Number 2-156]
IEC 60601-1:2005; 3rd Ed.	[Recognition Number 5-77]
IEC 60601-2-2:2009; 3rd Ed.	[Recognition Number 6-228]
AAMI/ANSI/IEC 60601-2-2:2009	[Recognition Number 6-229]
IEC 60601-2-18:2009; 3rd Ed.	[Recognition Number 9-61]
IEC 60601-2-18 (1996) Amend 1 2000	[Recognition Number 9-42]
IEC 62366: 2007	[Recognition Number 5-67]
ISO 8600-1:2005	[Recognition Number 9-37]
ISO 8600-1:2013	[Recognition Number 9-83]

8. Sterilization

HICURA hand instruments are provided non-sterile. They are reusable and need to be reprocessed before first and each subsequent use. HICURA hand instruments have to be reprocessed according to the validated procedures described in the instruction for use.

9. Biocompatibility

Biocompatibility of HICURA hand instruments has been evaluated according to the relevant parts of the AAMI ANSI ISO 10993 series for limited contact duration.

10 Conclusion

In summary, we believe the HICURA hand instruments are substantially equivalent with the predicate devices with respect to the general design approach, function, and the indications for use. The HICURA hand instruments raise no new concerns of safety or efficacy when compared to the predicate devices.